GigaGen Awarded U.S. BARDA Contract to Develop Recombinant Polyclonal Antibody Therapies for Botulinum Neurotoxins and an Additional Biothreat

The contract will provide an initial commitment of $19.6 million and up to $135.2 million over a six-year period, supporting drug manufacturing and phase 1 trials for the two programs

GigaGen's recombinant polyclonals are part of Grifols' robust innovation strategy and commitment to delivering the next generation of antibody drugs for patients and healthcare professionals

San Carlos, Calif., October 3, 2024 (GLOBE NEWSWIRE) -- GigaGen Inc., a biotechnology company advancing transformative antibody drugs for immunodeficiencies, infectious diseases and checkpoint-resistant cancers, and a subsidiary of Grifols, announced today that it has been awarded a contract by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). The award, valued at up to $135.2 million, is to develop a recombinant polyclonal antibody therapy for botulinum neurotoxins (BoNT) and a second biothreat of interest to the agency that will be determined at a later time.

"We are thrilled to have been awarded this BARDA contract and are proud to continue our collaboration with the U.S. government to advance innovative therapies against naturally emerging and intentional biological threats," said Carter Keller, senior vice president of Grifols and head of GigaGen. "GigaGen aims to change the way infectious diseases are treated with the world's only recombinant polyclonal antibody therapeutic platform. Building on our successful collaboration with the Department of Defense (DOD), this project demonstrates the versatility of our recombinant polyclonal antibody platform, which is ideally suited for rapid responses to imminent biological threats."

The BARDA project builds upon GigaGen's contract awarded by the U.S. DOD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) in 2022. The DOD project demonstrated the utility of GigaGen's first-in-class recombinant human polyclonal antibody discovery platform against biological threats, focusing on two BoNT variants. Following success in this program that included in vivo neutralization of the two botulinum neurotoxins, the BARDA project will support the manufacturing and initial clinical development of a drug product that targets all seven BoNT variants. BoNT, one of the most toxic biological substances, is produced by the bacterium *Clostridium botulinum* and can cause progressive muscle paralysis from the head to the rest of the body, which can be fatal if left untreated.

GigaGen recently received clearance from the U.S. Food and Drug Administration (FDA) for its Investigational New Drug (IND) application to initiate a Phase 1 clinical trial to evaluate the company's first recombinant polyclonal antibody therapeutic for the treatment of hepatitis B virus (HBV) infection, GIGA-2339. The company anticipates initiating the trial in Q4 2024.

This project has been funded in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number 75A50124C00049.

About GigaGen's platform

GigaGen's next-generation recombinant polyclonal platform offers a novel way to develop synthetic polyclonal antibody therapeutics in the laboratory, which are potentially more powerful than what a natural immune response can provide. Using high-throughput, single-cell genomic and protein engineering technology, GigaGen creates cell lines that express recombinant human antibodies against a diversity of infectious disease antigens. The polyclonal cell bank can then be used to continuously manufacture recombinant polyclonal products against the pathogen of interest at existing manufacturing facilities. GigaGen has demonstrated that its products are hundreds of times more potent than plasma-derived antibody therapies. They replicate and enhance the natural antibody diversity, encompassing thousands

of antibodies. This offers a significant advantage over monoclonal antibody therapies, as they can address the vast diversity of circulating pathogen variants and help prevent immune escape upon pathogen mutation.

About Grifols
Grifols is a global healthcare company founded in Barcelona in 1909 committed to improving the health and well-being of people around the world. A leader in essential plasma-derived medicines and transfusion medicine, the company develops, produces, and provides innovative healthcare services and solutions in more than 110 countries.

Patient needs and Grifols' ever-growing knowledge of many chronic, rare and prevalent conditions, at times life-threatening, drive the company's innovation in both plasma and other biopharmaceuticals. The company is focused on treating conditions across a broad range of therapeutic areas: immunology, hepatology and intensive care, pulmonology, hematology, neurology, and infectious diseases.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with over 390 across North America, Europe, Africa and the Middle East, and China.

As a recognized leader in transfusion medicine, Grifols offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion, in addition to clinical diagnostic technologies. It provides high quality biological supplies for life-science research, clinical trials, and for manufacturing pharmaceutical and diagnostic products. The company also supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 24,000 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety, and ethical leadership.

The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the Ibex-35 (MCE:GRF). Grifols non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ through ADRs (NASDAQ:GRFS).

GigaGen is advancing transformative antibody drugs for immunodeficiencies, infectious diseases and checkpoint resistant cancers by leveraging industry-leading, single-cell technologies. Its novel technology platforms uniquely capture and recreate complete immune repertoires as functional antibody libraries. This approach has enabled the creation of first-in-class recombinant polyclonal antibody therapies for the treatment of infectious diseases. In addition, GigaGen's lead oncology asset, GIGA-564, is an anti-CTLA-4 monoclonal antibody that has demonstrated improved anti-tumor efficacy and reduced toxicities in preclinical models through a unique mechanism of action.

For more information, please visit www.grifols.com or www.gigagen.com.

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